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Joseph Weathered

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT(S)	:	Peter J. WILK
SERIAL NO.	:	09/342,824
FILED	:	06/29/99
FOR	:	Apparatus and Method for Resonant Destruction of Tumors
GROUP ART UNIT	:	3737
EXAMINER	:	Eleni M. Mantis Mercader

Mail Stop Appeal Brief
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450*

BRIEF ON APPEAL

1. REAL PARTY IN INTEREST

The real party of interest in the present application is applicant's company Wilk Patent Development Corporation, a corporation formed under the laws of the State of New York, having a primary business address at 475 East 72nd Street, Suite 1L, New York, New York 10021. Although there has been no formal assignment of this application to that company, applicant has indicated an obligation to so assign.

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2. <u>RELATED APPEALS AND INTERFERENCES</u>

On information and belief, there are no cases currently on appeal before the Board which may have a bearing on the Board's decision in the instant Appeal.

3. <u>STATUS OF CLAIMS</u>

Claims 1-28 are pending in the application. Claims 1, 17, and 23 are the only independent claims. Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by prior art. Claims 1-28 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over prior art.

The appealed claims are set forth in Appendix A.

4. <u>STATUS OF AMENDMENTS</u>

All Amendments have been entered.

5. <u>SUMMARY OF THE CLAIMED SUBJECT MATTER</u>

A method for treating cancer, as set forth in independent claim 1, comprises detecting a tumor in a patient. The disclosure is rife with references to a "target tumor" (page 12, lines 1-3, 12-13; page 13. lines 5-8). The disclosure also describes in detail the transmission of ultrasonic pressure waves into a patient to monitor the resonance effects of generally lower test frequencies on a tumor. (E.g., page 11, lines 1 through 16; page 15, lines 6-11 and 19-20.)

The method of claim 1 further comprises applying mechanical pressure waves to said tumor at a mechanical resonance frequency of the entire tumor as a unitary body, to effectively destroy said tumor. (Page 3, lines 10-15.) Specifically, the specification states: "In a subsequent treatment procedure, control unit 18 generates, in the patient, treatment pressure waves of one or

more resonant frequencies and of effective amplitudes so that the tumor resonates with sufficient energy to be mechanically destroyed." (Page 12, lines 4-6.) It is the entire tumor that resonates, with the result that component parts are torn apart. (Page 12, lines 4-8.)

As set forth in independent claim 17, a medical treatment system comprises a carrier (34, Fig. 3) (page 3, lines 16-17; page 20, lines 20-21; page 16, lines 2-3 and 8-9), a plurality of electromechanical transducers (12a, 12b, 20, Figs. 1 and 3) mounted to the carrier (page 4, lines 6-7; page 20, lines 20-21; page 16, lines 2-3 and 8-9), an a-c current generator (14, Fig. 1) operatively connected to at least some of the transducers for energizing the transducers with electrical signals of a plurality of pre-established frequencies (page 11, line 8-9) to produce first pressure waves in the patient, and an acoustic signal processor (24, 26, 28, Fig. 2) (page 11, line 10; page 13, line 9) operatively connected to at least some of the transducers programmed to analyze incoming pressure waves to determine mechanical resonant characteristics of internal tissue structures of a patient, where the incoming pressure waves are generated by the internal tissue structures in response to the first pressure waves. (Page 11, lines 2-16; page 12, line 2, through page 13, line 4.) Pursuant to claim 17, the processor is programmed more particularly to determine which of the transducers is to be energized with which of the frequencies to resonantly overload a predetermined one of the tissue structures, thereby mechanically destroying the one of the tissue structures. (Page 11, lines 17-21.)

As set forth in independent claim 23, a method for performing a medical operation comprises placing a plurality of electromechanical transducers (12a, 12b, 20, Figs. 1 and 3) in pressure-wave-transmitting contact with a patient (page 11, lines 2-6; page 13, line 21, through page 14, line 9), energizing at least some of the transducers with an ultrasonic frequency to produce ultrasonic first pressure waves in the patient (page 15, lines 3-11), energizing at least one of the transducers with another frequency in a range below ultrasonic to produce second

pressure waves in the patient (page 15, lines 6-11 and 19-20), and analyzing ultrasonic third pressure waves produced at internal tissue structures of the patient in response to the first pressure waves to determine three dimensional shapes of the tissue structures and to monitor resonant motion of the tissue structures in response to the second pressure waves (page 15, lines 14-19).

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

The rejection of claim 1 under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,315,514 to Drewes et al. is to be reviewed on this appeal.

In addition, the rejection of claims 1-27 under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,871,446 to Wilk in view of U.S. Patent No. 5,526,815 to Granz et al. ("Granz" hereinafter) and further in view of U.S. Patent No. 4,315,514 to Drewes et al. is to be reviewed on this appeal.

7. ARGUMENT

A. Rejection of Independent Claim 1 Under 35 U.S.C. §102(b)

Claim 1 stands rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent No. 4,315,514 to Drewes et al. ("Drewes").

Appellant traverses the Examiner's rejection of claim 1 under 35 U.S.C. § 102(b) and maintains that claim 1 distinguishes the invention over the prior art and particularly over Drewes.

As set forth in claim 1, a method for treating cancer comprises detecting a tumor in a patient and applying mechanical pressure waves to the tumor at a mechanical resonance frequency of the entire tumor as a unitary body, to effectively destroy the tumor.

Drewes discloses the use of resonant frequencies to treat tumors. However, pursuant to the clear teachings of Drewes, the resonant frequency used is that of individual cells of a tumor, not of the tumor as a whole as set forth in Appellant's claim 1.

Pursuant to Appellant's invention as set forth in claim 1, mechanical pressure waves are applied to a tumor at a mechanical resonance frequency of the entire tumor, not at a mechanical resonance frequency of a ***cell*** of the tumor. The present invention contemplates that a tumor is a cohesive body which as a body resonating at one or more particular frequencies. In contrast, Drewes says nothing about a tumor body having a characteristic resonant frequency and instead teaches that resonant frequencies are those of the individual cells. Of course, any resonance of an individual cell occurs at a significantly higher frequency than resonance of an entire tumor body comprising enormous numbers of individual cells.

Drewes teaches away from the present invention by directing the attention of those of ordinary skill in the art to the high resonant frequencies of individual cells, as opposed to the resonant characteristics of entire tumors.

B. Rejection of Claim 1 Under 35 U.S.C. §103(a)

Claim 1 also stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,871,446 to Wilk in view of U.S. Patent No. 5,526,815 to Granz et al. ("Granz" hereinafter) and further in view of U.S. Patent No. 4,315,514 to Drewes et al.

Appellant traverses the rejection of claim 1 under 35 U.S.C. § 103(a) because none of the references relied on by the Examiner teaches or suggests the applying of mechanical pressure waves to a tumor at a mechanical resonance frequency of the entire tumor as a unitary body, to effectively destroy the tumor.

Wilk discloses a flexible carrier with a plurality of acoustic or electromechanical transducers for generating and detecting ultrasonic pressure waves in a patient. The Wilk reference is directed principally to an ultrasonic scanning device for diagnostic purposes or for monitoring internal organs during a minimally invasive surgical procedure wherein instruments are inserted into a patient. Wilk says nothing applying mechanical pressure waves to a tumor at

a mechanical resonance frequency of the entire tumor as a unitary body or as a whole, to effectively destroy the tumor.

Granz discloses the use of ultrasonic pressure waves to destroy tumors. However, the pressure waves are applied with a frequency and amplitude to destroy the tumors by local hyperthermia. Thus, the temperature of the tumor tissue is selectively raised by the application of ultrasonic pressure waves to destroy the tumor by heat. There is nothing in Granz which suggests the application of mechanical pressure waves to a tumor at a mechanical resonance frequency of the tumor to effectively destroy the tumor.

With respect to the technique for tumor destruction, the disclosure of the Drewes reference is considered closer than the disclosure of Granz to Appellant's invention as set forth in claim 1. Drewes discloses the use of resonant frequencies. However, as discussed above, the resonant frequency used in the Drewes disclosure is that of ***individual cells*** of a tumor, ***not of the tumor as a whole.***

In summary, none of the references relied on by the Examiner discloses or suggests the applying of mechanical pressure waves to a tumor at a mechanical resonance frequency of the entire tumor as a unitary body, to effectively destroy the tumor. The Wilk reference says nothing about resonance or tumor destruction. The Drewes reference discloses the use of mechanical vibratory resonance to destroy individual cells. The frequencies for the resonant destruction of individual cells are substantially higher than the frequencies for the resonant destruction of a tumorous cell mass as a whole. The Granz reference teaches the use of ultrasonic waves to destroy individual cells of a tumor by heating the individual cells. This method of cellular destruction does not involve resonance. Although the Granz patent uses the word "resonance" this term is applied to the vibration mode of a transducer, not a vibration mode of a tumor.

C. Rejection of Independent Claim 17 Under 35 U.S.C. §103(a)

Claim 17 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,871,446 to Wilk in view of U.S. Patent No. 5,526,815 to Granz et al. ("Granz" hereinafter) and further in view of U.S. Patent No. 4,315,514 to Drewes et al.

Appellant traverses the rejection of claim 17 under 35 U.S.C. § 103(a) for reasons discussed below.

As set forth in independent claim 17, a medical treatment system comprises a carrier, a plurality of electromechanical transducers mounted to the carrier, an a-c current generator operatively connected to at least some of the transducers for energizing the transducers with electrical signals of a plurality of pre-established frequencies to produce first pressure waves in the patient, and an acoustic signal processor operatively connected to at least some of the transducers programmed to analyze incoming pressure waves to determine mechanical resonant characteristics of internal tissue structures of a patient, where the incoming pressure waves are generated by the internal tissue structures in response to the first pressure waves. Pursuant to claim 17, the processor is programmed more particularly to determine which of the transducers is to be energized with which of the frequencies to resonantly overload a predetermined one of the tissue structures, thereby mechanically destroying the one of the tissue structures.

None of the references relied on by the Examiner, whether viewed singly or in combination, either discloses or suggests the apparatus of claim 17, wherein a processor linked to a plurality of electromechanical transducers is programmed to determine, based on incoming pressure waves generated by the internal tissue structures of a patient, (1) mechanical resonant characteristics of the internal tissue structures and (2) which of the transducers is to be energized with which frequencies to resonantly overload a predetermined one of the tissue structures, thereby mechanically destroying the one of the tissue structures.

The Wilk and Granz references disclose nothing about mechanical resonance and, more particularly, nothing about automatically (via a processor) determining mechanical resonant characteristics of internal tissues structures of a patient.

The Drewes reference does discuss the treatment of internal tissues of a patient with resonant pressure waves. However, Drewes does not teach or suggest the activation of electromechanical transducers by a processor which automatically analyzes incoming (reflected) pressure waves from internal tissues of a patient to determine resonant characteristics or a target

tissue structure. Instead, Drewes teaches away from the present invention as set forth in claim 17 by specifically disclosing the selection of a suitable resonant frequency through an *in vitro* testing operation (not an *in vivo* testing) wherein a biopsy is performed and the extracted tissue is analyzed outside the body of the patient to determine useful resonant characteristics.

Thus, the teachings of Drewes cannot suggest an apparatus with a processor linked to a plurality of electromechanical transducers and programmed to determine, ***based on incoming pressure waves generated by the internal tissue structures of a patient***, (1) mechanical resonant characteristics of the internal tissue structures and (2) which of the transducers is to be energized with which frequencies to resonantly overload a predetermined one of the tissue structures, thereby mechanically destroying the one of the tissue structures.

D. <u>Rejection of Independent Claim 23 Under 35 U.S.C. §103(a)</u>

Claim 23 stands rejected under 35 U.S.C. § 103(a) as being unpatentable over U.S. Patent No. 5,871,446 to Wilk in view of U.S. Patent No. 5,526,815 to Granz et al. ("Granz" hereinafter) and further in view of U.S. Patent No. 4,315,514 to Drewes et al.

Appellant traverses the rejection of claim 23 under 35 U.S.C. § 103(a) for reasons discussed below.

As set forth in independent claim 23, a method for performing a medical operation comprises placing a plurality of electromechanical transducers in pressure-wave-transmitting contact with a patient, energizing at least some of the transducers with an ultrasonic frequency to produce ultrasonic first pressure waves in the patient, energizing at least one of the transducers with another frequency in a range below ultrasonic to produce second pressure waves in the patient, and analyzing ultrasonic third pressure waves produced at internal tissue structures of the patient in response to the first pressure waves to determine three dimensional shapes of the tissue structures and to monitor resonant motion of the tissue structures in response to the second pressure waves.

None of the references relied on by the Examiner suggest the monitoring of resonant motion of tissue structure in a patient.

Again, the Wilk reference says nothing about resonance of tissue structures.

The Granz reference discloses a system for automatically treating tissue structures with ultrasonic energy to heat the tissue structures, wherein the system automatically monitors the location of the target tissue structures. Granz does not disclose or suggest the monitoring, detecting or sensing of resonant motion. In fact, Granz says nothing whatsoever about resonant motion.

Drewes discloses the destruction of tissue structures (individual biological cells) through the application of vibratory energy. However, Drewes says nothing about monitoring resonant motion of tissue structures inside a patient.

8. CONCLUSION

In summary, U.S. Patent No. 4,315,514 to Drewes et al. does not anticipate claim 1 and claims 1-28 present subject matter that is not obvious in view of U.S. Patent No. 5,871,446 to Wilk in view of Granz and Drewes et al.

For the foregoing reasons, the rejections of claim 1 under 35 U.S.C. § 102(b) and the rejection of claims 1-28 under 35 U.S.C. § 103(a) are deemed to be improper. Appellant therefore requests that the Examiner be reversed and the application remanded for proceedings towards issuance.

Respectfully submitted,

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Dated: October 27, 2005

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APPENDIX A

1. A method for treating cancer, comprising:

detecting a tumor in a patient; and

applying mechanical pressure waves to said tumor at a mechanical resonance frequency of the entire tumor as a unitary body, to effectively destroy said tumor.

2. The method defined in claim 1, further comprising determining said mechanical resonance frequency, the determining of said mechanical resonance frequency including:

generating a series of investigatory pressure waves of respective different preselected frequencies in a patient so that said investigatory pressure waves are transmitted to said tumor through overlying tissues;

during the generating of said investigatory pressure waves in the patient, monitoring responsive oscillatory motion of said tumor and at least some internal tissues of the patient proximate to the tumor, said responsive oscillatory motion arising as a result of the transmission of said investigatory pressure waves into the patient; and

determining said mechanical resonance frequency from the responsive oscillatory motion of said tumor and said internal tissues, said mechanical resonance frequency being a pressure wave frequency which results in a resonant loading of said tumor and essentially leaves said internal tissues undamaged.

3. The method defined in claim 2 wherein the applying of the mechanical pressure waves to said tumor includes generating, in the patient, treatment pressure waves of said mechanical

resonance frequency and of an effective amplitude so that said tumor resonates with sufficient energy to mechanically destroy said tumor.

4. The method defined in claim 3 wherein the generating of said investigatory pressure waves includes placing a substrate in contact with an external surface of the patient, said substrate carrying a plurality of electromechanical transducers, and further includes energizing said transducers with periodic voltages of said different preselected frequencies.

5. The method defined in claim 4 wherein the energizing of said transducers includes energizing each of said transducers with voltages of a plurality of different frequencies, the monitoring of responsive oscillatory motion of said tumor and at least some internal tissues of the patient proximate to the tumor including monitoring responsive oscillatory motion of said tumor and said internal tissues proximate to said tumor for each of said transducers and each of the frequencies with which the respective transducers are energized.

6. The method defined in claim 5 wherein the patient has skin surfaces in different planes and wherein the placing of said substrate in contact with an external surface of the patient includes positioning at least one of said transducers in pressure-wave transmitting contact with each of said skin surfaces.

7. The method defined in claim 5 wherein the generating of said treatment pressure waves includes energizing at least one of said transducers with a periodic voltage of said determined pressure wave frequency.

8. The method defined in claim 4 wherein the patient has skin surfaces in different planes and wherein the placing of said substrate in contact with an external surface of the patient includes positioning at least one of said transducers in pressure-wave transmitting contact with each of said skin surfaces.

9. The method defined in claim 2 wherein the monitoring of motion of said tumor and said internal tissues includes:

sensing pressure waves generated at a skin surface of the patient in response to motion of said tumor and said internal tissues; and

processing said pressure waves to determine said responsive oscillatory motion of said tumor.

10. The method defined in claim 9 wherein the processing of said pressure waves includes analyzing said pressure waves to determine three-dimensional shapes of internal tissue structures including said tumor and to determine modes and magnitudes of motions of said internal tissues structures.

11. The method defined in claim 3 wherein the generating of said treatment pressure waves includes placing an electromechanical transducer in contact with an external surface of the patient and energizing said transducer with a periodic voltage of said mechanical resonance frequency.

12. The method defined in claim 3 wherein the generating of said treatment pressure waves includes placing a substrate in contact with an external surface of the patient, said substrate carrying plurality of electromechanical transducers, and further includes energizing said transducers with a periodic voltage of said mechanical resonance frequency.

13. The method defined in claim 2 wherein the generating of said investigatory pressure waves includes placing an electromechanical transducer in contact with an external surface of the patient and energizing said transducer with periodic voltages of said different preselected frequencies.

14. The method defined in claim 2 wherein the monitoring of motion of said tumor and said internal tissues includes:

providing a multiplicity of probes each having sensors for determining motion;

inserting said probes into the patient; and

monitoring signal outputs of said sensors to determine motion of surfaces or boundaries of said tumor and said internal tissues.

15. The method defined in claim 1 wherein the applying of said said mechanical pressure waves to said tumor includes transmitting said mechanical pressure wave through overlying tissues of the patient.

16. The method defined in claim 1 wherein the applying of said said mechanical pressure waves to said tumor includes disposing at least one tranducer in the patient and energizing said transducer to generate said mechanical pressure waves.

17. A medical treatment system comprising:

a carrier;

a plurality of electromechanical transducers mounted to said carrier;

an a-c current generator operatively connected to at least some of said transducers for energizing said transducers with electrical signals of a plurality of pre-established frequencies to produce first pressure waves in the patient; and

an acoustic signal processor operatively connected to at least some of said transducers programmed to analyze incoming pressure waves to determine mechanical resonant characteristics of internal tissue structures of a patient, said incoming pressure waves being generated by said internal tissue structures in response to said first pressure waves, said processor being programmed more particularly to determine which of said transducers is to be

energized with which of said frequencies to resonantly overload a predetermined one of said tissue structures, thereby mechanically destroying said one of said tissue structures.

18. The system defined in claim 17, further comprising means operatively connected to said processor for identifying said one of said tissue structures.

19. The system defined in claim 18 wherein said means for identifying includes:

at least one electroacoustic transducer mounted to said carrier for producing primary ultrasonic pressure waves in the patient;

at least one acoustoelectric transducer mounted to said carrier for sensing secondary ultrasonic pressure waves produced at said internal tissue structures in response to said primary pressure waves; and

an ultrasonic wave analyzer operatively connected to said acoustoelectric transducer for determining three-dimensional shapes of said internal tissue structures of the patient by analyzing signals generated by said acoustoelectric transducer in response to said secondary pressure waves.

20. The system defined in claim 19 wherein said electroacoustic transducer is one of said electromechanical transducers and wherein said acoustoelectric transducer is one of said electromechanical transducers.

21. The system defined in claim 19 wherein said carrier includes a flexible web conformable to the patient.

22. The system defined in claim 19, further comprising a video monitor linked to said analyzer for displaying an image of said internal tissue structures.

23. A method for performing a medical operation, comprising:

placing a plurality of electromechanical transducers in pressure-wave-transmitting contact with a patient;

energizing at least some of said transducers with an ultrasonic frequency to produce ultrasonic first pressure waves in the patient;

energizing at least one of said transducers with another frequency in a range below ultrasonic to produce second pressure waves in the patient; and

analyzing ultrasonic third pressure waves produced at internal tissue structures of the patient in response to said first pressure waves to determine three dimensional shapes of said tissue structures and to monitor resonant motion of said tissue structures in response to said second pressure waves.

24. The method defined in claims 23 wherein said one of said transducers is energized *in seriatim* with a plurality of test frequencies in said range below ultrasonic, said another frequency being one of said test frequencies, the analyzing of said third pressure waves including

determining whether any of said test frequencies results in a resonant loading of a predetermined one of said tissue structures.

25. The method defined in claims 23, further comprising, upon determining that one of said test frequencies is a resonant frequency of said predetermined one of said tissue structures, energizing said transducer with said one of said test frequencies to destroy said predetermined one of said tissue structures.

26. The method defined in claims 23 wherein said transducers are all attached to a single flexible substrate, the placing of said transducers in pressure-wave-transmitting contact with the patient including conforming at least a portion of said substrate to the patient.

27. The method defined in claims 23, further comprising energizing a plurality of said transducers *in seriatim* with a plurality of test frequencies in said range below ultrasonic, the analyzing of said third pressure waves including identifying which of said transducers and which of said test frequencies, if any, induce a resonant loading of said predetermined one of said tissue structures.

28. The method defined in claims 23 wherein the analyzing of said third pressure waves to monitor resonant motion of said tissue structures in response to said second pressure waves

includes automatically comparing sizes and shapes of said tissue structures at a succession of times to determine changes in sizes and shapes of said tissue structures.